Data Submission Agreement (DSA) for the
International Myositis Assessment and Clinical Studies Groups (IMACS) Outcomes Repository

The National Institute of Environmental Health Sciences (NIEHS) is operating the IMACS Outcome Repository (Repository), as a Non-Genetic Study (Study) contained within the National Institutes of Health's (NIH) Protocol 94-E-0165 entitled "Studies in the natural history and pathogenesis of idiopathic inflammatory myopathies". The primary objective of the Repository is prospective validation of outcome measures for myositis trials, including response criteria known as the "Preliminary Definitions of Improvement" (definitions of flare or worsening), and clinical trial design issues. The goals are to develop standardized, validated outcome measures for myositis therapeutic trials, compare responses to therapies, develop predictors of therapeutic response, and further validate the various tools that are in the Repository. To accomplish the Repository's objectives and goals, pooled data from the Repository will be shared with other researchers for secondary or future research projects by applying to the Repository's Data Use Committee. A complete description of the Repository can be found at: http://www.niehs.nih.gov/research/resources/collab/imacs/outcomerepository.cfm.

Contributor: _____

Recipient: National Institute of Environmental Health Sciences, an institute of the National Institutes of Health

1. Contributor agrees to transfer to Recipient the Data (as described in Appendix 1), and Recipient agrees to accept and store Data for submission to the Repository for future use as part of the IMACS Outcomes Repository. Data will be individual phenotypic data and Contributor agrees to comply with 45 CFR 46 and any other applicable legal criteria that apply to the submission. REPOSITORY WILL NOT ACCEPT GENETIC DATA.

2. Data represents a significant investment on the part of the Contributor and Recipient agrees to retain control over the Data and to distribute only to IMACS collaborators according to the requirements for use of Repository data described in full at: http://www.niehs.nih.gov/research/resources/collab/imacs/researchguidelines.cfm), subject to applicable laws and NIH policy. Contributor reserves the right to distribute the Data to others and to use it for its own purposes.

3. Contributor certifies to the best of his/her knowledge and belief that the Data submitted to the Repository are accurate and further agrees to notify Recipient's Scientist as soon as possible if, upon review, the Contributor Scientist discovers Data quality concerns.

4. The Data was (will be) collected by the Contributor according to 45 CFR Part 46, Protection of Human Subjects, as applicable, under Federal Wide Assurance Number_____, assigned by the Office of Human Research Protection (OHRP) of the Department of Health and Human Services (DHHS), under
   Protocol # _____ and
   Protocol Title: _____.

5. Submission of Contributor's Data to Repository: (check which applies)
   ____ has been ruled exempt by Contributor's Institutional Review Board (IRB), or
   ____ has been approved by Contributor's IRB

6. In order to respect the privacy of the participants, the Recipient and the Recipient Scientist agree that it will not contact or make any effort to identify individuals, families, communities, tribes or populations which are or may be the sources of the Data. Recipient will place terms in any data sharing or use agreements to require third-party data users to agree to this provision as well.

7. Recipient will store Data on a secure server and limit data access, consistent with applicable U.S. Federal law and NIH policy.

8. For a period of two years following the locking of the database of the Contributor's study, listed in Appendix I of this DSA, Contributor Scientist shall have first option to publish on his/her own Data. Publications utilizing Contributor Scientist's submitted Data or subsets of such Data by other IMACS investigators shall require a separate Data Use Agreement and the approval of the intended study by the IMACS Research Advisory Committee. A subset of a Contributor Scientist's database may be utilized for a study prior to two years after the Contributor Scientist's database has been locked, if the Contributor Scientist and the IMACS Research Advisory Committee agree that this use would not infringe on the Contributor Scientist's publication of his/her primary data. (http://www.niehs.nih.gov/research/resources/collab/imacs/researchguidelines.cfm).

9. Contributor Scientist elects to: (choose one)
   - ☐ Become a member of the IMACS Research Advisory Committee and participate in review of data use proposals.
   - ☐ NOT become a member of the IMACS Research Advisory Committee.

10. This DSA is not transferable. Contributor agrees that additional data submission will require execution of a new DSA, in which the new data is designated. If the Contributor Scientist changes institutions and wishes to continue submitting data to the Repository, a new DSA in which the new institution acknowledges and agrees to the provisions of the DSA will be necessary.

11. Contributor agrees not to claim, infer, or imply endorsement by the United States Government, the Department of Health & Human Services, the National Institutes of Health, or the National Institute of Environmental Health Sciences. The Recipient, as an agency of the United States Government, assumes no liability except to the extent permitted under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

SIGNATURES BEGIN ON FOLLOWING PAGE

RECIPIENT INFORMATION AND AUTHORIZED SIGNATURE

Recipient Organization: National Institute of Environmental Health Sciences
Address: 111 T.W. Alexander Drive, Research Triangle Park, NC 27709
Name of Authorized Official: Elizabeth M. Denholm, Ph.D.
Title of Authorized Official: Director, Office of Technology Transfer
E-mail: denholme@niehs.nih.gov

_____ Date:_____
Authorized Signature for Recipient's Institution

Recipient Scientist:
Name: **Lisa G. Rider, M.D.**
Title: Deputy Chief, Environmental Immunology Group
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E-mail: riderl@niehs.nih.gov

READ AND UNDERSTOOD

_____ _____
Recipient Scientist Signature Date

CONTRIBUTOR INFORMATION and AUTHORIZED SIGNATURE

Contributor Scientist:
Name: _____
Address: _____
_____
_____
Phone: _____
Email: _____

READ AND UNDERSTOOD

_____ Date: _____
Signature of Contributor Scientist:

Contributor Organization: _____
Address: _____
_____
_____
Name of Authorized Official:_____
Title of Authorized Official:_____

Signature: _____ Date: _____

APPENDIX 1

INFORMATION ON DATA BEING TRANSFERRED TO RECIPIENT IN THIS DSA

Name of Contributor's Study or Trial: _____

Information on Database of the above Study or Trial: Please Check one item below (see clause 8 of this DSA)

_____Database was locked; Contributor has published results and is NOT requesting publication delay.

____ Database was locked on _____(date); a publication delay IS requested for studies that conflict with the contributors' primary publication(s).

_____ Database is not currently locked; Contributor IS requesting publication delay and will notify the IMACS Outcomes Repository Coordinators, Lisa Rider and Frederick Miller when database is locked.

Number of Patients: _____

Number of visits per patient: _____

Diagnoses: _____
_____
_____
_____

Data to be submitted to the Repository, will include: (check all below that apply):

_____1. IMACS Core Set Measures of Disease Activity (including Physician and Patient/Parent Global Activity Assessment, Manual Muscle Testing, Physical Function measured by the HAQ or CHAQ, muscle enzymes, and Extra-Muscular Activity assessed by the Myositis Disease Activity Assessment Tool), as outlined on the IMACS web site at http://www.niehs.nih.gov/research/resources/collab/imacs/diseaseactivity.cfm

_____ 2. Other IMACS Forms to be completed: These forms are located at
http://www.niehs.nih.gov/research/resources/collab/imacs/imacsforms.cf
Check all that apply:
____a. Core Patient Data
____b. Assessment of Trial Status
____c. Assessment of Study Outcomes
____d. Clinical Trial Design Features

_____ 3. Optional data for inclusion are listed below and these will be discussed in advance with Drs. Rider and Miller:
Check all that apply:
___ a. Assessment of Disease Damage (Physician and Patient/Parent Global Damage, Myositis Damage Index):
http:// http://www.niehs.nih.gov/research/resources/collab/imacs/docs/activity/phys_glob_act.pdf

___ b. Childhood Myositis Assessment Scale (CMAS)
http://www.niehs.nih.gov/research/resource/collab/imacs/docs/activity/cmas.pdf

___ c. Disease Activity Score (DAS)
http://www.niehs.nih.gov/research/resources/collab/imacs/restrict/forms/dis_act_score.pdf

___ d. Patient-reported Outcomes (SF-36 or CHQ-PF50)
http://www.niehs.nih.gov/research/resources/colab/imacs/patientoutcome.cfm